

App. No. 09/924,320  
Reply to Final Office Action

### REMARKS/ARGUMENTS

#### A. Summary of the Amendment

This is a full and timely response to the non-final Office Action dated November 15, 2005, and also to the Advisory Action mailed on February 2, 2006. Reexamination and reconsideration are courteously requested. By way of the present amendment, paragraph 0021 of the specification has been amended. Claims 1, 2, 4-26, and 28-33 remain pending in this application, with claims 1, 9, 22, and 29 being independent claims

The present amendment to the specification is merely for clarification of a passage. More particularly, the amendment clarifies the passage in paragraph 0021 that refers to FIGs. 1 and 2. Since only FIG. 1 *clearly and unambiguously* shows that a balloon outer layer is covering only a limited portion of a balloon inner layer, the reference to FIG. 2 is removed from this paragraph. The amendment does not raise new issues for the Examiner to consider, nor does it introduce new matter. Thus, entry of the amendment is proper under Rule 116.

#### B. Rejections Under 35 U.S.C. § 102

Claims 1, 4, 6 to 10, 12, 14, 17, 19 to 22, 24 to 25, and 28 to 32 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,913,871 ("Werneth"). The Applicant respectfully traverses these rejections.

Before addressing the prior art, a matter regarding the interpretation of the independent claims should be addressed. In section 9 of the final Office Action, the Examiner asserts that the phrase, "the outer first layer covering only a limited portion of the inner second layer" may be interpreted to include assemblies in which an outer layer covers the entirety of an inner layer instead of "only a limited portion" of the inner layer. The Examiner reiterates this point in the Advisory Action, asserting:

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"[t]he claims use the transitional phrase "comprising". This phrase is open-ended and does not exclude additional, unrecited elements. Thus, the outer layer may cover a limited portion and also other portions of the inner layer."

The Examiner also asserts in the final Office Action that "[i]n Figure 2 [of the present application], the outer first layer covers the entire inner second layer."

To start, it is respectfully pointed out that the open-ended form inherent from the use of the terms "comprising" and "including" does not remove the requirement for the prior art to teach or suggest "an outer first layer and an inner second layer, the outer first layer covering only a limited portion of the inner second layer" as recited in the independent claims in order for the claims to be anticipated. Werneth simply fails to do this.

The independent claims recite that the balloon outer layer covers only a limited portion of the balloon inner layer. A "portion" is, by definition, less than the whole. The American Heritage® Dictionary of the English Language, Fourth Edition (2000) defines "portion" as:

"A section or quantity within a larger thing; a part of a whole."

Further, the claims use the words "only" and "limited" to indicate that less than the entire inner layer is covered by the outer layer.

Regarding the Examiner's comment concerning the embodiment depicted in Figure 2 of the present application, it is respectfully pointed out that Figure 2 (and Figure 3 for that matter) only shows one cross-section of a balloon stent assembly. Although the outer layer 22 extends longitudinally across the entire inner layer 21 in the region depicted in the isolated cross-sectional view, nowhere in the specification or drawings is there a disclosure that all longitudinal cross-sectional views will reveal the same relationship between the outer layer 22 and the inner layer 21. In fact, paragraph 0021 of the original specification explains the opposite:

"As shown in Figures 1 and 2, the outer layer 22 is disposed on a limited area of the inner layer 21. It can be appreciated that the outer layer 22 may cover

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varying proportions and configurations of the inner layer 21 to achieve desirable stent retention."

Further, Figure 1 clearly depicts the outer layer 22 covering only a portion of the inner layer 21. Because Figure 1 more clearly represents the phrase, "the outer first layer covering only a limited portion of the inner second layer," the current amendment to the specification is made to remove any confusion that may result from the original wording in paragraph 0021. However, it should again be emphasized that Figure 2 does not necessarily depict an embodiment that falls outside of the claim language. The present amendment is not viewed as necessary, but is made as a concession to bring prosecution of this application to a close.

Turning now to the rejection of the claims, independent claim 1 relates to an apparatus for treating a vascular condition that includes, *inter alia*, a balloon having an outer first layer and an inner second layer. The outer first layer flows into gaps formed in the stent when the balloon stent assembly is heated to a predetermined temperature and retains the stent on the balloon during intravascular movement and the inner second layer does not flow into the gaps.

Independent claim 9 relates to a balloon stent assembly that includes, *inter alia*, a balloon including at least one non-tacky outer layer and at least one inner layer. When the balloon is heated at a predetermined temperature the outer layer flows into gaps formed in the stent while the inner layer does not flow.

Independent claim 22 relates to a method of retaining a stent on a balloon that includes an inner layer and an outer layer. The method includes, *inter alia*, the steps of mounting the stent onto the balloon and flowing an outer layer of the balloon into the gaps formed in the stent while an inner layer of the balloon does not flow, and while the balloon is heated.

Independent claim 29 relates to a balloon assembly that includes, *inter alia*, a balloon that includes an outer first layer and an inner second layer. A stent is disposed on the balloon, and a sheath is disposed on the stent and the balloon. The outer first layer flows into gaps formed in the stent when the balloon stent assembly is heated to a predetermined temperature, and retains the stent on the balloon during intravascular movement and the inner second layer does not flow into the gaps.

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Each of the independent claims includes a recitation of the above-discussed feature wherein the balloon outer layer covers only a limited portion of the inner second layer. Werneth fails to teach or suggest the claimed feature that a balloon outer layer that retains a stent covers only a limited portion of a balloon inner layer. Werneth discloses in FIGs. 2 and 4, and in the specification at column 6, lines 64 to 67 that a balloon may have a polymeric surface layer 110 formed by coating an underlying layer 120 or by coaxial extrusion. From FIG. 2 it is observed that the outer layer 110 appears to exist throughout the entire balloon 35, and there is no suggestion to the contrary in the figures or the specification. Because Werneth fails to teach or suggest at least this feature of the independent claims, it is respectfully submitted that the rejections under 35 U.S.C. § 102(b) should be withdrawn.

C. Rejections Under 35 U.S.C. § 103(a)

Claims 2, 16, 23, 26, and 33 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Werneth in view of WO 95/33422 ("Stolze"). Claims 5 and 18 are rejected as allegedly being unpatentable over Werneth in view of U.S. Patent No. 5,797,877 ("Hamilton"). Further, claims 11, 13, and 15 are rejected as allegedly being unpatentable over Werner in view of U.S. Patent No. 5,807,327 ("Green"). Each of these rejections is respectfully traversed.

Claims 2, 5, 11, 13, 15 to 16, 18, 23, 26, and 33 depend from their respective independent claims, some of the features of which are previously discussed. Therefore, these claims rely on the arguments presented above. Moreover, Stolze, Hamilton, and Green fail to compensate for the previously-discussed deficiencies of Werneth.

Hamilton teaches against an outer layer that flows into gaps formed in the stent when the balloon is heated to a predetermined temperature, as recited in both claims 1 and 9. Instead, Hamilton discloses using an adhesive between inner and outer layers in order to improve layer bonding. See Figure 2d and col. 6, ll. 20-38. Further, Stolze and Green also fail to teach a balloon having an outer layer and an inner layer. Stolze is cited for allegedly teaching pressurization of a balloon to depress a stent into the balloon surface. Green is cited for

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allegedly teaching that the use of urethane material will create a suitable force for retaining a stent. Both Stolze and Green are silent with regard to a two-layer balloon, and particularly one in which an outer layer covers only limited portions of an inner layer. Because none of the prior art, alone or in combination, teaches or suggests at least this feature of the independent claims, it is respectfully requested that the rejections under 35 U.S.C. § 103(a) be withdrawn.

#### D. Conclusion

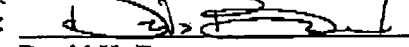
In view of Applicant's amendments and remarks, it is respectfully submitted that Examiner's objections and rejections have been overcome. Accordingly, Applicants respectfully submit that the application is now in condition for allowance, and such allowance is therefore earnestly requested. Should the Examiner have any questions or wish to further discuss this application, Applicants request that the Examiner contact the Applicants attorneys at the below-listed telephone number.

If for some reason Applicants have not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent abandonment on this application, please consider this as a request for an extension for the required time period and/or authorization to charge Deposit Account No. 50-2091 for any fee which may be due.

Respectfully submitted,

INGRASSIA FISHER & LORENZ

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